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Section 5 510(k) Summary

510(k) Owner:	Arthrosurface, Inc. 28 Forge Parkway Franklin, MA 02038 Tel: 508.520.3003 Fax: 508.528.4604
Contact:	Dawn Wilson VP, Quality & Regulatory
Date of Preparation:	December 16, 2011
Trade Name:	CheckMate™ Metatarso-Phalangeal (MTP) Arthrodesis System
Common Name:	Arthrosurface Toe Plate System
Device:	Plate, fixation, bone
Classification Regulation:	Regulation Number 888.3030
Device Class:	Class II
Review Panel:	Orthopedic
Product Code:	HRS

Device Intended Use

The CheckMate™ Metatarso-Phalangeal (MTP) Arthrodesis System is intended for use in stabilization and fixation of the 1st MTP joint in the foot for fusion, osteotomy, nonunion, malunion or revision surgery.

Device Description

The CheckMate™ Metatarso-Phalangeal (MTP) Arthrodesis System consists of anatomically contoured bone plates and screws which are intended to be used for surgical fusion (arthrodesis) of the 1st MTP joint. The plate is available in both left and right configurations. Locking, non-locking and interfragmentary screws are included as part of the system.

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Substantial Equivalency:

The intended use, materials, design features and application of the Proposed Device are substantially equivalent to the following previously cleared and commercially marketed devices:

- DePuy ALPS Small Bone Locked Plating System K101240
- Arthrex Low Profile Plate and Screw System K052614
- Synthes 2.4 mm/2.7 mm Variable Angle (VA)-LCP Forefoot/Midfoot System K100776

Comparative static and dynamic four point bending test results, along with comparative dimensional analyses were used to support equivalence to predicate devices.

The fundamental scientific technology of the proposed device has not changed relative to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

FEB - 6 2012

Arthrosurface, Inc.
% Ms. Dawn Wilson
28 Forge Parkway
Franklin, MA 02038

Re: K113762
Trade/Device Name: CheckMate™ Metatarso-Phalangeal (MTP) Arthrodesis System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS, HWC
Dated: December 16, 2011
Received: December 21, 2011

Dear Ms. Wilson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 Indications for Use Statement

510(k) Number (if known): K113762

Device Name: CheckMate™ Metatarso-Phalangeal (MTP) Arthrodesis System

Indications for Use:

The CheckMate™ Metatarso-Phalangeal (MTP) Arthrodesis System is intended for use in stabilization and fixation of the 1st MTP joint in the foot for fusion, osteotomy, nonunion, malunion or revision surgery.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for (Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K113762